



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,997	09/23/2002	Barrie Hayes-Gill	469.1094	5818
21171 7590 12/13/2007 STAAS & HALSEY LLP SUITE 700 1201 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER BERTRAM, ERIC D	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

mn

Office Action Summary	Application No. 10/089,997	Applicant(s) HAYES-GILL ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/3/07 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 25-47 have been considered but are moot in view of the new ground(s) of rejection, necessitated by applicant's amendment.

3. Examiner is aware that in the interview on 9/19/07, the changes were agreed to be sufficient to overcome the prior art. However, upon further consideration, the amendments still read upon Lewis et al. (US 6,115,624). The Examiner still agrees that Lewis et al. (and the rest of the cited prior art) does not disclose a processor that only processes ECG signals received only from electrodes placed on the abdomen of the mother. However, as currently claimed, as long as the detector processes only ECG signals from the electrodes on the abdomen to determine the heart rate of the fetus, and not ECG signals from any other source, the claim limitation is met. Since Lewis et al. does not process any other ECG signals other than those received from the array placed on the abdomen of the mother, Lewis cannot possibly process other ECG signals. The fact that Lewis requires the use of acoustic signals in addition to the ECG

signals to determine the heart rate is not precluded by the current claim language.

Suggested claim language to overcome this newly discovered deficiency is recited below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 25-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 25 recites the limitation "means for determining the heart rate" in the last clause of the claim. It is unclear whether or not this heart rate is the heart rate of the fetus, or the heart rate of the mother. Since claims 26-47 depend from claim 25, they are rendered indefinite by their association. For Examination purposes, it is assumed that this heart rate is the heart rate of the mother.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 25-27, 31 and 42 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al. (US 6,115,624, hereinafter Lewis).

12. Lewis discloses an apparatus for detecting fetal and/or maternal heart rate, wherein a plurality of ECG electrodes may be located on a lower surface of a pad which is secured to a pregnant women's abdomen (see col. 2, lines 33-65). Fetal and/or maternal ECG activity may be detected with the array of electrodes (see col. 2, lines 50-55), and processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60) by processing only ECG signals received from electrodes on the abdomen. Lewis does not specifically disclose that the processor utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats of the mother by determining when the ECG peaks reach a maximum (i.e., QRS peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between QRS peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that detection of the maternal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate by well known and accepted medical methods.

13. With respect to claims 26 and 27, Lewis discloses that the array of electrodes includes at least two detectors to detect the heart beats of the fetus, each detector including at least two electrodes (active electrodes 42 and common or reference electrode 41; see col. 4, line 55 - col. 5, line 6).

14. With respect to claim 31, Lewis discloses that the ECG signal may be utilized by the processor circuitry to derive the fetal and/or maternal heart rate, which may then be displayed on a video display or other monitoring device (see col. 2, lines 58-61). The processed data may be displayed in a useful manner, e.g., on digital display or a chart recorder (see col. 9, lines 1-10).

15. With respect to claim 42, Examiner considers the apparatus portable.

16. Claims 30 and 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis.

17. With respect to claims 30, 32, and 36-37, bandpass filters are well known to filter noise components from a detected ECG. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that bandpass filters are utilized in the signal processing of the ECG in order to reduce noise and obtain a more accurate ECG signal.

18. With respect to claims 33 and 35, Lewis teaches that the processor circuitry may compare the detected signals to a database stored in the memory circuitry to further facilitate the heart rate information in the signals. For example, the database may include information such as standard maternal and/or fetal heart signals which may be compared to the detected signals in order to more accurately derive the desired actual heart rate (see col. 10, lines 43-51).

19. With respect to claims 34 and a portion of claim 40, subtracting a maternal component from a composite ECG is well known in order to obtain the fetal ECG only

(e.g., see U.S. Patent No. 4,781,200 to Baker at col. 8, lines 20-40 or col. 10, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis to utilize the standard maternal heart signal stored in the above-described database in order to obtain the fetal ECG only and monitor the well-being of the fetus.

20. With respect to claims 38-39 and a portion of claim 40, Lewis discloses that the processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60). Lewis does not specifically disclose that the processor utilizes ECG peaks in order to determine the fetal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats by determining when the ECG peaks reach a maximum (i.e., ECG peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between ECG peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis such that detection of the fetal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the fetal heart rate by well known and accepted medical methods.

21. With respect to claim 41, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to aggregate the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates.

Allowable Subject Matter

22. Claims 28, 29 and 43-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

23. The following claim 25 drafted by the examiner and considered to distinguish patentably over the art of record in this application, is presented to applicant for consideration:

25. (Currently Amended) An apparatus for detecting the heart rate of a fetus, the apparatus comprising:

a detector to detect heart beats of the fetus, the detector including at least two electrodes placed on the abdomen of the mother for detecting ECG signals; and

a processor, coupled to the detector, adapted to determine the heart rate of the fetus by only processing the ECG signals received from the at least two electrodes and without using any other detected signals, the processor further including:

means for detecting heart beats of the mother by determining when the ECG signals reach a maximum; and

means for determining the heart rate of the mother by determining the time interval between adjacent heart beats, so as to determine the heart rate of the mother using only the processed ECG signals.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

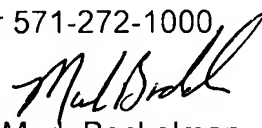
Application/Control Number:
10/089,997
Art Unit: 3766

Page 9

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766


Mark Bockelman
Primary Examiner
Art Unit 3766

EDB